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RELATIONSHIP BETWEEN THE DEVELOPMENT OF ELECTRONIC HEALTH RECORDS AND HOSPITAL ACCREDITATION DECISIONS IN FRANCE: RESULTS FROM THE E-SI (PREPS-SIPS) STUDY
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OBJECTIVES: To make eHealth technology more efficient, particularly for the quality and safety of care, the French Ministry of Health (DGOS) launched the national "Hopital numérique 2012-2017" program, a strategic development plan for the modernization of health information technology. The aim of this study was to assess the impact of the development of electronic health records (EHR) on the accreditation results of French hospitals performed by the HAS (French National Authority for Health). **METHODS:** This retrospective study included all of the acute care hospitals accredited between October 2012 and April 2014. Three national databases were used: national accreditation database, oSIS (observatoire des systèmes d'information de santé-2012), and IPAQSS (indicateurs pour l'amélioration de la qualité et la sécurité des soins-2012). National data were provided by the DGOS and HAS, together with methodological support. We developed an ordered Logit model, where the polytomous dependent variable was ordered according to the following descriptions: full accreditation, recommendation, reservation, or delay in the accreditation decision. The independent variables were the proportion of EHR used (full, partial, or no EHR); type of hospital (teaching, private non-profit, for-profit, or other public hospital); accuracy of the care, with versus without home care hospitalization; and geographic region. **RESULTS:** The study included 679 hospitals; 21% had full accreditation, 45% recommendation, 25% reservation, and 9% a delay in accreditation. We found that the higher the number of full EHR used, the better the accreditation decision ($p<0.001$). We also observed that the higher the number of partial EHR used, the better the accreditation decision ($p=0.002$). Finally, the accreditation decision was also better for for-profit hospitals ($p<0.001$), private non-profit hospitals ($p=0.005$), and in the southeast of France ($p=0.02$). **CONCLUSIONS:** Our findings suggest that the development of EHR in acute care hospitals is associated with a higher performance in accreditation decisions in France.

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SERIOUS ADVERSE DRUG EVENTS REPORTED TO THE FOOD AND DRUG ADMINISTRATION (FDA): ANALYSIS OF THE FDA ADVERSE EVENT REPORTING SYSTEM (FAERS) 2006-2011 DATABASE
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OBJECTIVES: In 1998, the Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS) (formerly AERS) was launched by the FDA as a post-marketing safety surveillance program to capture adverse drug events (ADEs) and medication errors. From 1998 to 2005, it was found that the number of serious and fatal ADEs reported to the FDA increased by 2.6-fold and 2.7-fold, respectively. The purpose of this study was to document current trends in serious and fatal ADE reports. **METHODS:** We conducted a retrospective analysis of the 2006-2011 FAERS database. Information on patient demographics, primary suspect drug, outcomes, and other variables were obtained from data files. Non-US reports and reports from clinical trials were excluded. Outcomes were recoded into three categories: death, disability (disability or congenital anomaly), and all other serious outcomes (hospitalizations, requiring intervention, or life-threatening, or other serious outcomes). We determined the number of reports by year, the types and sources of reports, and age-wise distribution of serious ADEs. A list of drugs with more than 1,000 reports of serious ADEs was compiled and subgroups of important drugs were identified **RESULTS:** A total of 245,265 reports of deaths (53,447), disabilities (20,305), and other serious outcomes (171,513) were reported representing 206,087 person-reports. The percentage of reports involving death increased from 17.3% in 2006 to 27.0% in 2011. Analgesics, antihypertensives, and antipsychotics were the most common drugs involved in serious reports of ADEs. Drugs with more than 1,000 serious reports of ADEs included 2 drugs currently withdrawn from market, 4 drugs under the FDA Risk Evaluation and Mitigation Strategies (REMS) program, 11 specialty drugs, 3 biologic drugs, and others. **CONCLUSIONS:** A substantial number of serious ADEs were reported from 2006-2011. Drugs under the REMS program, specialty drugs, and biologic drugs contribute to a significant number of serious ADEs.

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SENSITIVITY, SPECIFICITY AND LEVEL OF AGREEMENT BETWEEN DIFFERENT CRITERIA USED TO DIAGNOSE THE METABOLIC SYNDROME
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OBJECTIVES: Numerous diagnostic criteria of the metabolic syndrome exist including the recent 2009 World Health Organization definition, criteria for National Cholesterol Education Program Adult Treatment Panel III (NCEP-ATP III), International Diabetes Federation (IDF) and European Group for Study of Insulin Resistance (EGIR). The multiplicity of definitions makes comparing studies with older criteria difficult. Our objective was to compute sensitivity, specificity, positive (PPV) and negative predictive values (NPV) and level of agreement between WHO standard and other definitions to determine which criteria performs best when comparing estimates from previous studies. **METHODS:** The NHANES 2009-10 and 2011-2012 demographics, examination and laboratory data formed our cohort. Prevalence estimates using all criteria were calculated. Sensitivity, specificity, PPV and NPV of all criteria keeping the WHO criteria as gold standard were computed. Kappa statistics to determine strength of agreement between WHO criteria relative to other definitions were estimated. **RESULTS:** WHO criteria yielded the highest prevalence at 22.2% followed by NCEP (19.1%), IDF (9.8%) and EU criteria (6.2%). Sensitivity of the NCEP criteria was the highest at 86.2% followed by IDF (38.6%) and EU (25.9%) criteria. Specificity of the NCEP criteria was highest at 100% followed by EU (99.3%) and IDF (98.3%) criteria. The PPV of the NCEP criteria was 100% while those of EU and IDF criteria were 91.8% and 86.9% respectively. Similarly the NPV was highest for the NCEP criteria followed by the EU (99.3%) and IDF (98.3%) criteria. The kappa-statistics showed highest agreement with the NCEP criteria (kappa=0.90) while the IDF (kappa=0.46) and EU criteria (kappa=0.33) displayed moderate and fair levels of agreement respectively with the WHO criteria. **CONCLUSIONS:** Our findings demonstrate that NCEP criteria displayed best performance parameters relative to WHO criteria and may serve as alternative to the WHO criteria when comparing other definitions used in older studies to current studies.

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IN THEIR OWN WORDS: SOCIAL LISTENING FOR "REAL-WORLD BENEFITS" FROM PRESCRIPTION AND OTC PRODUCTS
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OBJECTIVES: The objective of this study was to evaluate "real-world benefit" discussions from publically available de-identified sources (social media and internet forums) that can be obtained through social listening. **METHODS:** A third party vendor collected posts from Facebook and Twitter over the previous year for a variety of 15 prescription and over-the-counter (OTC) products. Data vocabularies were standardized using a vernacular to MedDRA dictionary for medical conditions and a custom curated vernacular dictionary for drugs and OTC products. Next, noise was systematically removed via natural language processing and each post was characterized as a Mention (drug mentioned but no adverse events) or a Proto AEs (potential adverse event mentioned within the context of drug use). Finally, the data was de-identified prior to making it available to the research team who then manually reviewed each post and collected "real-world benefit" attributes. **RESULTS:** Overall 2159/7529 (29%) of Mentions and Proto AEs contained "real-world benefit" information; of the 2159 posts, 1207 (56%) were positive benefits discussions and 952 (44 %) discussed lack of effect. Of the positive benefits discussions (N=1207), 94 (8%) contained benefit time-to-onset, 28 (2%) contained duration of benefit, 125 (10%) indicated partial benefit, 514 (43%) indicated full benefit, 37 (3%) contained benefits discussion within the context of cost, 196 (16%) contained benefits discussion within the context of adverse events, and 138 (11%) contained benefits information as compared to other treatment options. **CONCLUSIONS:** Social listening has the potential to provide a large amount of information about "real-world benefit" as discussed from the consumers'/patients' perspective. This is the first step in understanding how Social Listening can contribute to better characterization of benefit/risk profiles using the consumers' own voice.

PHP95
IS THERE AN ASSOCIATION BETWEEN POTENTIALLY INAPPROPRIATE PRESCRIBING IN THE ELDERLY AND HOSPITALIZATION AND MORTALITY? A LONGITUDINAL, LARGE COHORT STUDY
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OBJECTIVES: Prevalence of potentially inappropriate prescribing (PIP) of harmful medications in the elderly has been widely investigated, but it remains unclear whether PIP is predictive of adverse events. Our study objective was to determine whether exposure to PIP is linked to increased rates of hospitalization and mortality. **METHODS:** We performed a retrospective analysis using the Italian Regione Emilia-Romagna (RER) longitudinal administrative healthcare database of all elderly patients ($\geq$ 65 years) from 2003 to 2013. The RER database includes de-identified, fully-linkable demographic, hospital, and pharmacy claims data for all residents in the region. PIP exposure initiated upon the dispensing of a medication that "should always be avoided" based on the Maio criteria. To estimate PIP exposure we computed the number of days supplied for each medication of interest (using Defined Daily Doses) plus 30 days. An exposure period spanned the duration of consecutive PIP dispensings. An event, the composite outcome of hospitalization or death, was attributed to PIP if it occurred during an exposure period. Rate ratios and 95% confidence intervals (CI) were estimated by Poisson generalized estimating equations modeling. **RESULTS:** The 1,471,179 elderly individuals living in the RER contributed a total of 10,369,120 person-years (PY) of follow-up time and experienced a total of 1,973,878 events. The unadjusted event rate was 1.572 (95% CI: 1.562, 1.580) times greater among patients exposed to PIP compared to those not exposed (2.87 events/10 PY vs. 1.82 events/10 PY). The unadjusted mortality rate was 1.473 (95% CI: 1.458, 1.488) times greater with PIP exposure (0.51/10 PY vs. 0.35/10 PY). **CONCLUSIONS:** These results indicate that exposure to PIP may be associated with higher hospitalization and mortality rates in elderly patients. This analysis, using a large cohort of patients, sheds light on the importance of reducing PIP in this population.

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AN INTENSIVE STUDY OF ADVERSE EVENTS IN THE MEDICAL UNIT OF A NIGERIAN TEACHING HOSPITAL
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OBJECTIVES: Adverse Events (AEs) has proven to be a significant cause of hospital admissions, with prevalence rate ranging from 6.5-26.1% and this constitute a significant problem with serious consequences and a challenge for public health. This intensive study is aimed at determining the prevalence of AEsas well as to assess the cause, nature, severity, preventability and outcomes in a Nigerian teaching hospital and to determine the class of suspected drugs most commonly implicated. **METHODS:** A three months observational study of 221 consecutive adult patients of the Lagos University Teaching Hospital medical in-patient ward and out-patient clinic. Epi-info statistical software, (Version 3.4.3, 2007) was used to analyze and determine prevalence, causality, severity and preventability. A significance level of $p < 0.05$ was used. **RESULTS:** The prevalence of AEs was 17.6% (95% CI; 12.9, 23.3) with 30 (79.5%) of these presenting at admission and 8(20.5%) developing during hospitalization. The World Health Organization (WHO) causality